

Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/821,710  
Filed : April 8, 2004  
Page 10 of 19 of July 12, 2007 Amendment

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Remarks

Claims 44 and 77-141 are pending in the subject application. By this Amendment, Applicants have amended the claims as indicated above to overcome all of the rejections set forth in the January 12, 2007 Final Office Action. All pending claims as amended herein recite the embodiment indicated to be allowable in the January 12, 2007 Final Office Action, i.e. the embodiment of allowable claim 101. This Amendment, therefore, places all of the pending claims in condition for allowance and should be entered under 37 C.F.R. § 1.116.

Restriction between product claims.

On pages 2-3 of the January 12, 2007 Final Office Action, the Examiner alleged that newly submitted claims 114-144 [sic: 114-141] are directed to an invention that is independent or distinct from the invention originally claimed. The Examiner alleged that claims directed to two inventions are pending in the subject application, designating claims 44 and 77-113, directed to an isolated nucleic acid molecule, as "Invention 1," and designating claims 114-141, directed to a eukaryotic cell comprising the nucleic acid molecule, as "Invention 2."

The Examiner then alleged that Inventions 1 and 2 "are distinct because invention 1 does not require the cell of invention 2, and further because invention 2 requires the presence of cells, it also requires search and examination that are non-coextensive with that required for invention 1." On this reasoning the Examiner concluded that the restriction is proper.

The Examiner stated that since Applicants have received an

Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/821,710  
Filed : April 8, 2004  
Page 11 of 19 of July 12, 2007 Amendment

action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits, and withdrew claims 114-141 from consideration as allegedly directed to a non-elected invention, referring to 37 CFR 1.142(b) and MPEP §821.03. The Examiner did agree to consider rejoinder of claims from Invention 2 that require a nucleic acid commensurate in scope with that of invention 1 when allowable subject matter is identified for invention 1.

*Applicants' response*

Applicants respectfully disagree with the restriction between the claims directed to an isolated nucleic acid, and claims directed to cells comprising the nucleic acid. In fact, despite setting forth the requirement for restriction on pages 2-3 of the January 12, 2007 Final Office Action, the Examiner proceeded to examine claims 114-141, e.g. on page 5 of thereof. Regardless, in view of Applicants' amendment herein to recite allowable subject matter in the claims of purported Invention 1, and the Examiner's agreement to consider rejoinder of the claims of purported Invention 2 that are commensurate in scope with the allowable claims of Invention 1, Applicants submit that the restriction is moot.

Applicants look forward to the allowance of all of the claims pending upon entry of this Amendment.

Priority

On pages 3-4 of the January 12, 2007 Final Office Action, the Examiner alleged that pending claim 44 has an effective filing

Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/821,710  
Filed : April 8, 2004  
Page 12 of 19 of July 12, 2007 Amendment

date of March 19, 1999, and all of the pending claims have an effective filing date no earlier than March 19, 1999.

Applicants respectfully disagree. For example, while the Examiner alleged that the priority applications reveal no support for a first ribonucleotide sequence of greater than 20 consecutive nucleotides, Applicants respectfully submit that support for the phrase may be found, *inter alia*, on page 25, line 21 of PP 2499, filed March 20, 1998. However, in view of Applicants' amendments herein, Applicants submit that the issue is moot.

#### Oath/Declaration

Applicants are pleased to note that on page 4 of the January 12, 2007 Final Office Action the Examiner stated that the oath or declaration is no longer considered to be defective.

#### Rejection under 35 U.S.C. § 112, first paragraph - New matter

On page 4 of the January 12, 2007 Final Office Action, the Examiner rejected claim 103 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement.

In response, to advance prosecution but without conceding the correctness of this rejection, Applicants have herein cancelled claim 103 without prejudice to their right to pursue the subject matter of claim 103 in a related application. Accordingly, the rejection of claim 103 under 35 U.S.C. 112, first paragraph, is moot.

Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/821,710  
Filed : April 8, 2004  
Page 13 of 19 of July 12, 2007 Amendment

RECEIVED  
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JUL 12 2007

Moot Rejections under 35 U.S.C. §§ 102 and 103

On pages 5-6 of the January 12, 2007 Final Office Action, the Examiner rejected claims 44, 77, 80-87, 90, 91, 97, 98, 104-106, 110, 111, 114, 118, 119, 125-127, 129, 130, and 131 under 35 U.S.C. 102(b) as allegedly anticipated by Agrawal et al. (WO 94/01550, of record).

On page 7, the Examiner rejected claim 102 under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al. (WO 94/01550, of record).

On pages 7-8, the Examiner rejected claims 44, 78, 79, 88, 89 and 112 and 113 under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al. (WO 94/01550, of record) in view of Day et al. (Proc. Nat Acad. Sci. USA 88:6721-6725, 1991).

On pages 8-10, the Examiner rejected claims 44, 88, 89, 99, 100, 112 and 113 under 35 U.S.C. § 103 as allegedly unpatentable over Agrawal et al (WO 94/01550, of record) in view of Shewmaker et al. (US patent 5,107,065).

On page 10, the Examiner rejected claims 44, 90, 92 and 94 under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al. (WO 94/01550, of record) in view of McGarry et al. (Proc. Nat. Acad. Sci. USA 83:399-403, 1986).

On page 11, the Examiner rejected claims 44, 90 and 92 under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al (WO 94/01550, of record) in view of Powell-Coffman et al (Dev. Biol. 178:472-483, 1996).

Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/821,710  
Filed : April 8, 2004  
Page 14 of 19 of July 12, 2007 Amendment

On page 12, the Examiner rejected claims 44, 90, 93 and 95 under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al (WO 94/01550, of record) in view of Barabino et al (Mech. Dev. 63:133-143, 1997).

On pages 12-13, the Examiner rejected claims 44, 90 and 96 under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al. (WO 94/01550, of record) in view of Swamynathan et al. (J. Virol. 71(4): 2873-2880, 1997).

On pages 13-14, the Examiner rejected claims 44 and 107 under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al (WO 94/01550, of record) in view of Schreiber et al (US Patent 5,858,981).

On pages 14-15, the Examiner rejected claims 44, 108 and 109 under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al. (WO 94/01550, of record) in view of Dhalla et al (Bichem. J. 336(2): 373-379, 1998).

#### *Applicants' response*

In response, to advance prosecution but without conceding the correctness of any of the foregoing rejections, Applicants have herein amended the claims to recite the embodiment of claim 101 which was indicated to be allowable on page 15 of the January 15, 2007 Final Office Action.

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JUL 12 2007

Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/821,710  
Filed : April 8, 2004  
Page 15 of 19 of July 12, 2007 Amendment

Accordingly, Applicants respectfully submit that each of the foregoing rejections is moot. Moreover, Applicants respectfully submit that all of the rejection and objection in the January 12, 2007 Final Office Action are moot in view of this Amendment.

The February 23, 2007 and March 6, 2007 "Third Party Submission Under C.F.R. 1.99 In Published Application"

Applicants note that a third party has filed two submissions under 37 C.F.R. § 1.99. These submissions are defective and should not have been made of record.<sup>1</sup>

Regardless, for the convenience of the Examiner, Applicants are making of record by the concurrently filed Information Disclosure Statement an April 24, 2007 Amendment filed in Reexamination Control No. 90/007,247, which is a reexamination of related U.S. Patent No. 6,573,099. The April 24, 2007 Amendment addresses all but one of the references submitted by the third party.

The claims being discussed in the reexamination are different from the claims pending in the subject application. Nonetheless, the element of a "stuffer fragment" is common to

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<sup>1</sup> The February 23, 2007 and the March 6, 2007 "Third Party Submission Under C.F.R. 1.99 In Published Application" are each untimely under 37 C.F.R. § 1.99(e) and should both be stricken from the record for being untimely. The subject application published November 25, 2004. Each of the references submitted with the third party submissions have been available since January 14, 2003 or earlier. The third party submissions have been filed more than two (2) years after the publication of the subject application and over four (4) years after the latest patent or publication was available. The third party submissions are untimely.

Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/821,710  
Filed : April 8, 2004  
Page 16 of 19 of July 12, 2007 Amendment

certain claims of the patent in reexamination and all of the pending claims of the subject application, and a January 24, 2007 Office Action in the re-examination on page 19 acknowledged that "The Fire et al. patent [U.S. 6,506,559] and the PGPUB 10/282,996 application differ [from the '099 patent] by not specifically teaching a nucleic acid stuffer fragment as recited in claims 5 and 9 of the instant '099 patent." Applicants also point out that the April 24, 2007 Amendment in the reexamination includes a Declaration under 37 C.F.R. §1.131 to remove as a reference several of the documents submitted by the third party. Furthermore, the claims of the subject application as amended herein recite additional features (e.g., an intron) which are neither taught nor suggested by the submitted references.

Accordingly, besides being an improper submission, the submission is of references which do not anticipate or make obvious the invention as currently claimed in the subject application.

Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/821,710  
Filed : April 8, 2004  
Page 17 of 19 of July 12, 2007 Amendment

RECEIVED  
CENTRAL FAX CENTER  
JUL 12 2007

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(d)

In accordance with their duty of disclosure under 37 C.F.R. §1.56, Applicants direct the Examiner's attention to the document listed below and on Form PTO-1449 attached hereto as Exhibit A. The document including all exhibits is available to the Examiner and to the public as the imaged file-wrapper of Reexamination Control No. 90/007,247 on the PAIR system of the U.S. Patent and Trademark Office.

This Information Disclosure Statement is being filed after the issuance of a final Office Action. According to 37 C.F.R. §1.97(d) this Information Disclosure Statement shall be considered if accompanied by the fee set forth in 37 C.F.R. §1.17(p) and a statement under 37 C.F.R. § 1.97(e).

The required fee set forth in 37 C.F.R. §1.17(p) is ONE HUNDRED AND EIGHTY DOLLARS (\$180.00) and the undersigned authorizes the Commissioner to charge the \$180.00 fee to Deposit Account No. 03-3125.

Pursuant to 37 C.F.R. § 1.97(e)(2), the undersigned states that no item disclosed in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three (3) months prior to the filing of this Information Disclosure Statement. The submitted document is dated April 24, 2007, which is less than three (3) months prior to this filing.



Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/821,710  
Filed : April 8, 2004  
Page 18 of 19 of July 12, 2007 Amendment

Accordingly, this Information Disclosure Statement is to be considered.

1. April 24, 2007 Amendment In Response To Non-Final Office Action By Patent Owner In Ex Parte Reexamination, filed in connection with Reexamination Control No. 90/007,247.

Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/821,710  
Filed : April 8, 2004  
Page 19 of 19 of July 12, 2007 Amendment

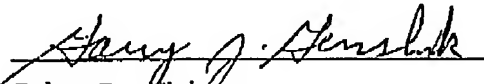
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JUL 12 2007

*Conclusion*

Applicants respectfully request that the Examiner advance the subject application to allowance. If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the \$1,020.00 fee for a three-month extension of time and the \$180.00 fee for the Information Disclosure Statement, is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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## **Exhibit A**

**of Amendment In Response To January 12, 2007 Final  
Office Action, Petition For A Three-Month Extension  
of Time, And Information Disclosure Statement  
Under 37 C.F.R. §1.97(d) filed July 12, 2007 in  
U.S. Serial NO. 10/821,710, filed April 8, 2004**